Correspondance

ever-evolving tool and the CONSORT group welcomes suggestions to further improve the quality of reports of randomized controlled trials. Unfortunately, in this instance, Chan and colleagues have apparently overlooked the existing CONSORT documents. Nevertheless, we congratulate them for their excellent study and for highlighting the issue of clinical importance.

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References

- Chan KBY, Man-Son-Hing M, Molnar FJ, Laupacis A. How well is the clinical importance of study results reported? As assessment of randomized controlled trials. CMAJ 2001;165(9): 1197-202.
- Clarke M, Chalmers I. Discussion sections in reports of controlled trials published in general medical journals: islands in search of continents? 7AMA 1998;280:280-2.
- Docherty M, Smith R. The case for structuring the discussion of scientific papers. BMJ 1999; 318:1224-5.
- Moher D, Schulz KF, Altman DG, for the CONSORT group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Ann Intern Med 2001;134:657-62.
- Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne DR, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann In*tern Med 2001;134:663-9.

onsidering their study's objectives, I was surprised that Karen Chan and colleagues did not explain why they evaluated only 10% (27/266) of available randomized controlled trials. This is especially interesting as both previous studies they referenced^{2,3} evaluated more studies, 102 and 45 respectively, and therefore were more precise.

Further, why weren't the proportions in Table 3 accompanied by 95% confidence intervals, particularly when the reporting of confidence intervals was one of the criteria Chan and colleagues used to evaluate randomized controlled trials?

When one refers to Diem and Lentner's Scientific Tables,4 it is troubling to note the imprecision of the proportions reported by Chan and colleagues1 (e.g., 22/27 = 81%, confidence interval [CI] 62-94%; 20/27 = 74%, CI 54-89%; 18/20 = 90%, CI 68-99%; 2/18 = 11%, CI 1-35%; 13/18 = 72%, CI 47-90%; 17/27 = 63%, CI 42-81%; 11/27 =41%, CI 22-61%; 10/20 = 50%, CI 27-73%; 15/20 = 75%, CI 51-91%). Apparently, the upper and lower limits of many of these confidence intervals could lead to differing conclusions. For example, although Chan and colleagues found that 74% of investigators (20/27) discussed the clinical significance of their findings,1 this estimate is also consistent with values as low as 54% and as high as 89%.

In closing, I would argue that the determination of study precision should be part of the planning process for all studies, not just randomized controlled trials. Such as step would strengthen both the statistical and clinical integrity of any planned study.

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References

- Chan KBY, Man-Son-Hing M, Molnar FJ, Laupacis A. How well is the clinical importance of study results reported? An assessment of randomized controlled trials. CMAJ 2001;165(9): 1197-202
- Moher D, Dulberg CS, Wells GA. Statistical power, sample size and their reporting in randomized controlled trials. *JAMA* 1994;272:122-4.
- Pocock SJ, Hughes MĎ, Lee RJ. Statistical problems in reporting of clinical trials: a survey of three medical journals. N Engl J Med 1987; 317:426-32.
- Diem K, Lentner C, editors. Scientific tables. 7th ed. Basel (Switzerland): JR Geigy; 1970. p. 85-6.

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[The authors respond:]

T pon rereading the revised CON-SORT statement,1 we still do not see an explicit recommendation that authors should discuss the clinical importance of their study results. We do not believe that the discussion of such an important component of the reporting of randomized controlled trials should have been relegated to the accompanying explanation and elaboration paper.² We are delighted that the CONSORT statement is an ever-evolving tool and suggest that in the next version the checklist explicitly state that authors should (1) report and justify the magnitude of the minimal clinically important difference and (2) discuss and justify their interpretation of the clinical importance of the study result in relation to that difference.

We agree with Bart Harvey's comment. However, the goal for our study was to highlight an important short-coming in the reporting of randomized controlled trials rather than to document the precise frequency of this phenomenon. We believe that we were able to accomplish this goal with our relatively small sample size.

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References

- Moher D, Schulz KF, Altman DG, for the CONSORT group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Ann Intern Med 2001;134:657-62.
- Chan KBY, Man-Son-Hing M, Molnar FJ, Laupacis A. How well is the clinical importance of study results reported? An assessment of randomized controlled trials. CMAJ 2001;165(9): 1197-202.
- Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne DR, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;134:663-9.